Application No. 09/996,438
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Docket No. 5724-03-BHJ

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the number listed below.

Respectfully submitted,

Barry H. Jacobsen
Attorney for Applicants
Reg. No. 43,689

Warner-Lambert Company
201 Tabor Road
Morris Plains, New Jersey 07950
Phone (973) 385-7072
Fax (973) 385-3117

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MARKED UP VERSION TO SHOW CHANGES

1. A pharmaceutical composition comprising:

an acid salt of a sympathomimetic amine; and

at least one combination inhibitor, said combination inhibitor selected from the group consisting of an amino polymer, a salt of a transition metal and combinations thereof,

wherein each said combination inhibitor is a single component and is present in amounts sufficient to interfere with the isolation of said sympathomimetic amine and to interfere with the conversion of said sympathomimetic amine to other pharmacologically active compounds without significantly altering the release of said sympathomimetic amine from said pharmaceutical composition as compared to the undenatured composition.

2. The pharmaceutical composition according to claim 1 further comprising at least one reaction inhibitor, wherein said reaction inhibitor is present in amounts sufficient to interfere with the conversion of said sympathomimetic amine to other pharmacologically active compounds without significantly altering the release of said sympathomimetic amine from said pharmaceutical composition as compared to the undenatured composition.

3. The pharmaceutical composition according to claim 1 further comprising at least one separation inhibitor, wherein said separation inhibitor is present in amounts sufficient to interfere with the isolation of said sympathomimetic amine without significantly altering the release of said sympathomimetic amine from said pharmaceutical composition as compared to the undenatured composition.

4. The pharmaceutical composition according to claim 2 further comprising at least one separation inhibitor, wherein said separation inhibitor is present in amounts sufficient to interfere with the isolation of said sympathomimetic amine without significantly altering the release of said sympathomimetic amine from said pharmaceutical composition as compared to the undenatured composition.

5. The pharmaceutical composition according to claim 1 wherein said sympathomimetic amine is selected from the group consisting of pseudoephedrine hydrochloride, pseudoephedrine sulfate, ephedrine hydrochloride and phenylpropanolamine hydrochloride.

6. The pharmaceutical composition according to claim 5 wherein said sympathomimetic amine is pseudoephedrine hydrochloride.

7. The pharmaceutical composition according to claim 1 wherein said other pharmacologically active compound is selected from the group consisting of methamphetamine, amphetamine, methacathinone and cathinone.

8. The pharmaceutical composition according to claim 7 wherein said other pharmacologically active compound is methamphetamine.

9. The pharmaceutical composition according to claim 1 wherein said amino polymer is a copolymer of methyl methacrylate, butyl methacrylate and dimethylaminoethyl methacrylate.

10. The pharmaceutical composition according to claim 9 wherein said amino polymer is the neutralized hydrochloride salt form of the

copolymer of methyl methacrylate, butyl methacrylate and dimethylaminoethyl methacrylate.

11. The composition according to claim 1 wherein said transition metal is selected from the group consisting of iron, cobalt, copper, chromium, manganese, nickel, zinc and combinations thereof.

12. The composition according to claim 1 wherein the anion of said transition metal salt is selected from the group consisting of chloride, oxide, sulfate and gluconate.

13. The composition according to claim 1 wherein said transition metal salt is selected from the group consisting of ferric chloride, ferric oxide, ferrous sulfate, ferrous chloride, ferrous gluconate, ferrous oxide, zinc gluconate, copper gluconate and combinations thereof.

14. The pharmaceutical composition according to claim 13 wherein said transition metal salt is selected from the group consisting of ferrous gluconate, zinc gluconate, copper gluconate and combinations thereof.

15. The pharmaceutical composition according to claims 2 or 4 wherein said reaction inhibitor is selected from the group consisting of water insoluble polyhydroxy compounds, non-polymeric water soluble polyhydroxy compounds, solvent soluble ester compounds and combinations thereof.

16. The pharmaceutical composition according to claim 15 wherein said water insoluble polyhydroxy compound is selected from the group consisting of ethylcellulose, cellulose and combinations thereof.

17. The pharmaceutical composition according to claim 15 wherein said non-polymeric water soluble polyhydroxy compound is selected from the group consisting of fructose, glycerin, sorbitol, lactitol, mannitol, xylitol, maltitol, galactose and combinations thereof.

18. The pharmaceutical composition according to claim 15 wherein said solvent soluble ester is selected from the group consisting of glycerin esters, esters of glycerin polymers, sorbitol esters, propylene glycol esters, polyethylene glycol esters, sucrose esters, esters of ethoxylated fatty alcohols and combinations thereof.

19. The pharmaceutical composition according to claims 3 or 4 wherein said separation inhibitor is selected from the group consisting of water soluble cellulose compounds, polysaccharide gums, polyethylene oxide polymers, acrylic acid polymers, starches, magnesium aluminum silicates, polyvinylpyrrolidones, clays and combinations thereof.